

FROM : TOP GLOVE SUN BHD

PHONE NO. :

AUG.26 1999 06:11PM P1

AWARDED
MS ISO 9002**TOP GLOVE SDN. BHD.**

(Medical Latex Glove Manufacturer and Exporter)

(Company No. 220483 T)

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THE DIRECTOR
DIVISION OF SMALL MANUFACTURERS
ASSISTANCE (HF7-220)
OFFICE OF HEALTH AND INDUSTRY PROGRAMS
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857
TEL. NO. : 001-301-443-6597 Ext. 116 Ok 146
FAX. NO. : 001-301-443-8818

August 26, 1999

Attn: Mr. John Stigi

Dear Sir,

Re: Comment on the **proposed change** regulation
of FDA for Medical Devices

Your circular letter pertaining to the above matter refers.

We have the following **comments** on the **proposed change regulation**:-

(1) Expiration Date

In order to **determine** the shelf-life of different type of **Medical** gloves, we **would** appreciate if FDA can provide us **the** method to **determine** the shelf-life.

(2) Labeling for Medic31 Gloves2.1 Powder level

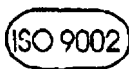
The new **regulation** of **no more than 120 mg powder** per glove on the powdered surgeon's and powdered patient examination gloves is **too stringent** for **medical glove** industry as **powder** is **necessary** for **easy donning purpose**. WC would recommend **powder level** to be no more than **200 mg powder per gloves** which is **SMG** (Standard Malaysian Glove) standard

2.2 protein level

The **protein level** should be expressed in **µg/g** if it is to be **appeared in labeling**. We would not agree to put content of no more than **1,200 µg extractable protein** per glove in the labeling as only **small group** of **hypersensitivity** individual is sensitive to **allergic** of **natural rubber**.

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The existing caution statement of protein allergy should be sufficient to warn the users on skin sensitivity problem. Further, the protein labeling should only be meant for the manufacturer who want to claim for low protein labeling on their product.

Your kind consideration to our comments is highly appreciated as any change in FDA regulation will have great impact on the medical glove industry.

Thank you and looking forward to hear from you

Have a nice day

Best Regards,



Loo Sun Nooi
Assistant QA Manager

c.c. Mr. Wee-Chai Lim, Managing Director

c.c. MARGMA, Mr. Andrew Tan

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LSN/Cb/FDA-5/MyDw(Miscusall)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: August 27, 1999

From: Assistant to the Director, Division of Small Manufacturers Assistance, HFZ-220

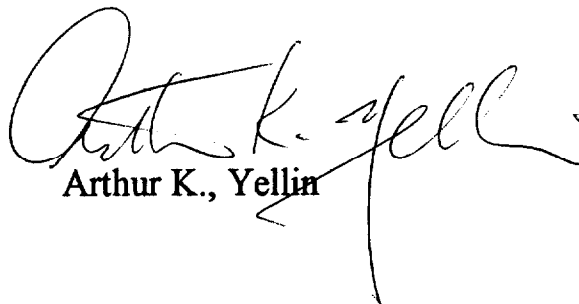
Subject: Comments on proposed regulation

Re: Docket No. **98N-03** 13

To: Dockets Management Branch, **HFA-305, 5630** Fishers Lane, room 1061

Please file the attached two copies of comments under Docket No. **98N-03** 13, "Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice," which published on July **30, 1999** (64 **FR** 41709).

Thank you!


Arthur K., Yellin